K003761

510(k) Notification November 30, 2000
Medical Packaging Corporation
NAT™ - Nucleic Acid Transport

MAY 31 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

DATE OF SUMMARY PREPARATION: November 30, 2000

COMPANY:

Medical Packaging Corporation
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CONTACT PERSON: Richard Curtis

DEVICE NAME: NAT™ - Nucleic Acid Transport

DEVICE CLASSIFICATION: Class I, Culture Media, Non Propagating

COMMON NAME: Transport Media

PREDICATE DEVICE(S):

FlexTrans™ Transport Media
(K970597)
Bartels Diagnostics Division
Baxter Diagnostics

INTENDED USE:

Medical Packaging Corporation's NAT™ - Nucleic Acid Transport is intended for use as a stabilizing transport medium when collecting and shipping clinical specimens for either Chlamydia trachomatis or Neisseria gonorrhoeae laboratory testing.

Materials Provided: The Female collection kit includes the following items:

- 2 sterile, pre-scored, medium sized Dacron swabs pouched separately
- One tube containing 1.0 ml of NAT media liquid.

The swab pack and the transport tube are combined into a larger outer pouch.

The Male collection kit includes the following items:

- 1 sterile, pre-scored, thin sized Dacron swab in a pouch
- One tube containing 1.0 ml of NAT media liquid.

The swab pack and the transport tube are combined into a larger outer pouch.

Comparison to Predicate Device

Similarities:

The *NAT – Nucleic Acid Transport* and FlexTrans™ Transport Media are similar in that:

- Both media are intended to take a clinical sample from point of collection to point of testing with no interim tests required
- Both media can be used for non-culture based assays of Chlamydia trachomatis or Neisseria gonorrhoeae
- Neither media can be used for culture based assays of Neisseria gonorrhoeae
- Both media are liquids that can be stored at room temperature
- Both media use swabs for the collection of specimens.

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Differences:

The *NAT – Nucleic Acid Transport* and FlexTrans™ Transport Media are different in that:

- *NAT – Nucleic Acid Transport* cannot be used for culture based assays. It is intended as a transport for nucleic acid based tests, only.
- *NAT – Nucleic Acid Transport* does not contain antibiotics or sucrose. These ingredients in FlexTrans™ and similar transport media are intended to ensure viability of host cells in the specimen to minimize the loss of organisms during transport. Unlike culture based tests, nucleic acid based tests are effective without the need for these ingredients.
- Both media contain salts
- *NAT – Nucleic Acid Transport* utilizes a chemical mechanism (detergent) rather than a mechanical mechanism (glass beads) to aid in the release of biological material from the collection device.

Conclusion:

Medical Packaging Corporation's *NAT – Nucleic Acid Transport* is substantially equivalent to the *FlexTrans™ Transport Media.*

All used materials should be treated as potentially infectious and biohazardous. Proper handling and disposal methods should be employed.

Date: 12/4/00

Richard Curtis
Manager, Quality Control/ Quality Assurance
Medical Packaging Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 31 2001

Ms. Deborah L. Zumerling
Director Business Development
Medical Packaging Corporation
941 Avenida Acaso
Camarillo, CA 93010

Re: 510(k) Number: K003761
Trade/Device Name: NAT™ – Nucleic Acid Transport
Regulation Number: 866.2900
Regulatory Class: I
Product Code: LIO
Dated: April 5, 2001
Received: April 9, 2001

Dear Ms. Zumerling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NAT™ - Nucleic Acid Transport
510(K) Number K003761

INDICATION FOR USE:
Medical Packaging Corporation's NAT™ - Nucleic Acid Transport is intended for use as a stabilizing transport medium when collecting or shipping clinical specimens for either Chlamydia trachomatis or Neisseria gonorrhoeae DNA or RNA testing. The transport is designed for use with swabs sampled from male urethral or female endocervical sources. This transport has been tested with four nucleic acid systems: Abbott LCX®, BD Probe Tec™ ET, Roche COBAS AMPLICOR™ and Gen-Probe®Pace 2®.

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003761

PRESCRIPTION USE X